BONE MORPHOGENETIC PROTEIN (BMP)

Description: Bone morphogenetic proteins (BMP) are members of the family of transforming growth factors. At present, some 15 different BMPs have been identified, all with varying degrees of cartilage and/or bone inductive properties. Two recombinant proteins are now commercially available, rh-BMP-2 and rh-BMP-7. These products have been investigated as an alternative to bone autografting in a variety of clinical situations, including spinal fusions, internal fixation of fractures, treatment of bone defects, and reconstruction of maxillofacial conditions. Rh-BMPs are delivered to the bone grafting site as part of a surgical procedure; a variety of carrier and delivery systems has been investigated. Carrier systems, which are absorbed over time, function to maintain the concentration of the rh-BMP at the treatment site, provide temporary scaffolding for osteogenesis, and prevent extraneous bone formation. Carrier systems have included inorganic material, synthetic polymer, natural polymers, and bone allograft. The rh-BMP and carrier may be inserted via a delivery system, which may also function to provide mechanical support. For interbody spinal fusion, delivery systems have included interbody fusion cages. The carrier and delivery system are important variables in the clinical use of rh-BMPs. For example, different clinical applications will require different dosages of rh-BMP with different carriers and delivery systems. Therefore, the results of one clinical application cannot be extrapolated to others.

At the present time, two rh-BMPs and associated carrier/delivery systems have received approval from the U.S. Food and Drug Administration (FDA). Osteogenic Protein-1™ (OP-1™) consists of rh-BMP-7 and bovine collagen, which is reconstituted with saline to form a paste. The addition of carboxymethylcellulose forms a putty. The InFUSE® system consists of rh-BMP-2 on an absorbable collagen sponge carrier.

OP-1™ (Stryker Biotech) has received two FDA approvals through the Humanitarian Device Exemption (HDE) process. An HDE is available to those devices intended for fewer than 4,000 patients per year; as part of this process, the manufacturer is not required to demonstrate unequivocal benefit, but only “probable” benefit. OP-1™ received the following labeled indications:
• “OP-1™ Implant is indicated for use as an alternative to autograft in recalcitrant long bone non-unions where use of autograft is unfeasible and alternative treatments have failed.”

• “OP-1™ Putty is indicated for use as an alternative to autograft in compromised patients requiring revision posterolateral (intertransverse) lumbar spinal fusion, for whom autologous bone and bone marrow harvest are not feasible or are not expected to promote fusion. Examples of compromising factors include osteoporosis, smoking and diabetes.”

The InFUSE® Bone Graft (Medtronic Sofamor Danek) in conjunction with one of two interbody fusion devices, either the LT-Cage Lumbar Tapered Fusion Device or the Inter Fix RP Threaded Fusion device, received FDA approval through the premarket approval (PMA) process:

• The device is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history, function deficit, and/or neurological deficit and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis at the involved level or retrolisthesis. The InFUSE™ Bone Graft/LT-CAGE™ devices are to be implanted via an anterior open or a laparoscopic approach. The InFUSE® Bone Graft/INTER FIX™ Threaded Fusion Device; and InFUSE® Bone Graft/INTER FIX™ RP Threaded Fusion Device are to be implanted via an anterior open approach only. Patients receiving the InFUSE® Bone Graft/Interbody Fusion Device should have had at least six months of non-operative treatment prior to treatment with the InFUSE® Bone Graft/Interbody Fusion Device. (Note: A collagen sponge consists of the carrier, while the interbody fusion device is a delivery system.)

• For the treatment of acute, open fractures of the tibial shaft
• For sinus augmentations, and for localized alveolar ridge augmentations for defects associated with extraction sockets.

The INFUSE/MASTERGRAFT™ (Medtronic Sofamor Danek), which includes the InFUSE® bone graft, received approval through the Humanitarian Device Exemption (HDE) process in October 2008. This device is approved for “repair of symptomatic, posterolateral lumbar spine pseudoarthrosis.” It is intended to address a small subset of patients for whom autologous bone and/or bone marrow harvest are not feasible or are not expected to promote fusion.

Both OP-1™ and the InFUSE® Bone Graft/LT-Cage Lumbar Tapered Fusion device are contraindicated in patients who are pregnant, who may be allergic to any of the materials contained in the devices, who have an infection near the area of the surgical incision, who have had a tumor removed from the area of the implantation site or currently have a tumor in that area, or who are skeletally immature.
Policy:

Use of recombinant human bone morphogenetic protein-2 (rhBMP-2), including but not limited to, InFUSE® bone graft may be considered **MEDICALLY NECESSARY** for the following indications:

- As an adjunct to anterior lumbar interbody fusion procedure; OR
- As an adjunct to treatment of open fracture of the tibial shaft, which has been stabilized with intramedullary nail fixation after appropriate wound management; OR
- For repair of symptomatic, posterolateral lumbar spine pseudoarthrosis in patients for whom autologous bone and/or bone marrow harvest are not feasible or are not expected to promote fusion.

Use of recombinant human bone morphogenetic protein-7 (rhBMP-7), including but not limited to, Osteogenic Protein-1™ (OP-1™ Implant) may be considered **MEDICALLY NECESSARY** for the following indications:

- As an alternative to autograft in recalcitrant long bone non-unions where use of an autograft is unfeasible and alternative treatments have failed; OR
- As an alternative to autograft in compromised patients requiring revision posterolateral (intertransverse) lumbar spinal fusion, for whom autologous bone and bone marrow harvest are not feasible or are not expected to promote fusion.

Use of recombinant human bone morphogenetic protein-2 (rhBMP-2) or recombinant human bone morphogenetic protein-7 (rhBMP-7) is considered **INVESTIGATIVE** for all other indications, including but not limited to:

- As an adjunct to thoracic and cervical fusion procedures;
- As initial treatment or revision of posterolateral spinal fusion, except as indicated above;
- As management of early stages of osteonecrosis of the vascular head or femoral shaft;
- As an adjunct to distraction ostogenesis (Ilizarov procedure)
- Craniofacial applications including, but not limited to, periodontal defect regeneration, cleft palate repair, cranial defect repair, restoration and maintenance of the alveolar dental ridge.

Coverage: **Pre-Certification/Pre-Authorization: No.**

However, bone morphogenetic protein (BMP) is not covered when used for conditions other than spinal and long-bone conditions listed above.

When BMP is used for **indications** that are considered investigative or not medically necessary, any procedures performed in conjunction with BMP will not be covered. This includes, but is not limited to, professional, facility, and anesthesia services as well as supplies.
Coding: The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT:
20930 Allograft, morselized, or placement of osteopromotive material, for spine surgery only (list separately in addition to code for primary procedure)
20931 Allograft, structural, for spine surgery only (list separately in addition to code for primary procedure)

ICD-9 Procedure:
84.52 Insertion of recombinant bone morphogenetic protein

Policy History:
Medical and Behavioral Health
Policy Committee Review:
Developed December 10, 2008
Reviewed November 11, 2009
Revised Formatting July 20, 2010
Reviewed November 10, 2010
Coding Updated July 19, 2011
Reviewed November 9, 2011

Cross Reference:
Humanitarian Use Devices, IV-11
Spinal Fusion: Lumbar, IV-87

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